K102267

510(k) Summary

SEP 10 2010

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: August 6, 2010

Device name

Proprietary name: Elecsys® Ferritin CalCheck 5
Common name: Ferritin CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys Ferritin CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys Ferritin CalCheck (K981281).

Device description

The Elecsys Ferritin CalCheck 5 is a liquid product consisting of ferritin from human liver in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys Ferritin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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Device comparison—similarities

Table 1 below presents the similarities between Elecsys Ferritin CalCheck 5 and the predicate device, Elecsys Ferritin CalCheck (K981281).

Table 1. Device Comparison—Similarities between Candidate and Predicate Devices

Characteristic	Elecsys Ferritin CalCheck 5 (Candidate Device)	Elecsys Ferritin CalCheck (K981281)
Analyte	Ferritin (human liver)	Same
Format	Liquid	Same
Handling	Mix gently by inversion to ensure homogeneity.	Same
Matrix	Human serum matrix	Same

Device comparison—differences

Table 2 below presents the differences between Elecsys Ferritin CalCheck 5 and the predicate device, Elecsys Ferritin CalCheck (K981281).

Table 2. Device Comparison—Differences between Candidate and Predicate Devices

Characteristic	Elecsys Ferritin CalCheck 5 (Candidate Device)	Elecsys Ferritin CalCheck (K981281)
Intended Use	The Elecsys Ferritin Calcheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Ferritin reagent on Elecsys 1010 or 2010 immunoassay analyzers.
Levels	Five	Three
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 5 hours

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Performance characteristics	The Elecsys Ferritin CalCheck 5 was evaluated for value assignment and stability.
Conclusion	The data demonstrate that the performance of the Elecsys Ferritin CalCheck 5 is substantially equivalent to that of the predicate device, Elecsys Ferritin CalCheck (K981281).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
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Roche Diagnostics
c/o Sarah Baumann
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SEP 10 2010

Re: k102267
Trade Name: Elecsys Ferritin CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: August 6, 2010
Received: August 9, 2010

Dear Ms. Baumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K102267

SEP 10 2010

Device Name: Elecsys Ferritin CalCheck 5

Indications for Use: The Elecsys Ferritin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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